REMARKS

Claims 1-12 were examined. Claims 1 and 2 are amended. Claim 4 and claims 13-22 are cancelled. Claims 1-3 and 5-12 remain in the Application.

The Patent Office provisionally rejects claims 1-3 and 5-10 under nonstatutory obviousness-type double patenting grounds. The Patent Office rejects claims 1-12 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. After Final Claim Amendments

Applicant amends claims 1 and 2. The amendments are non-substantive and not intended to change the scope of either claim. Accordingly, Applicant respectfully requests that the Patent Office enter the amendments.

B. Obviousness-type Double Patenting

The Patent Office provisionally rejects claims 1, 3 and 5-10 on the ground of nonstatutory obviousness-type double patenting in view of claims 1 and 3-9 of copending Application Serial No. 10/166,854.

Applicant respectfully submits the obviousness-type double patenting rejection is improper. Applicant directs the Patent Office to 35 U.S.C. §131 which provides that:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the court against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. if a divisional application is directed solely to subject matter described and claimed in the original application as filed, the

> Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

Applicant also directs the Patent Office to MPEP §804.01 which provides that:

> 35 U.S.C. 121 authorizes the *>Director< to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 24 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.
>
> The prohibition against holdings of double patenting applies to requirements for restriction between the related subjects treated in MPEP §806.04 through *>§806.05(j)<, namely, between combination and subcombination thereof, between subcombinations disclosed as usable together, between process and apparatus for its practice, between process and product made by such process and between apparatus and produce made by such apparatus, etc., so long as the claims in each applications are filed as a result of such requirement.

The Patent Office previously imposed a restriction requirement in U.S. Patent Application No. 10/166,854, the application to which the present application relates as a continuation-in-part. Accordingly, Applicant respectfully requests that the Patent Office withdraw the obviousness-type double patenting rejection.

C. 35 U.S.C. §103(a): Rejection of Claims 1-10

The Patent Office rejects claims 1-10 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,162,202 of Sicurelli, et al., (Sicurelli). Sicurelli discloses a flexible irrigation

syringe tip for irrigating and delivering medication to intra-tooth canals during endodontic route canal treatment. *See* column 4, lines 15-18.

> As shown in FIG. 4 flexible syringe needle 10c of syringe 1c may have dispensing ports as lateral side ports dispensing fluid substantially transverse to a longitudinal axis of flexible syringe needle 10c, or a plurality of longitudinally extending, spaced apart lateral side ports 17c, wherein the plurality of lateral side ports 17c extend between the fluid discharge end 15c and connecting end 12c.

Column 4, lines 51-57.

With respect to Figure 9, Sicurelli discloses that a flexible syringe needle may be connected to remote pump 200 for directing fluid at a controlled rate to a tooth canal. See column 5, lines 28-31. The pump may have a pressure control to increase pressure to allow flow through smaller gauge needles and for safely avoiding excess pressure. See column 5, lines 41-43. Finally, the flexible syringe needle may have a pressure control means 500 communicating with pressure sensor 550 for controlling the flow of the fluid discharged from the flexible needle. See column 5, lines 48-51.

Independent claim 1 describes a system including a needle with an opening and at least one aperture located at a predetermined distance from the opening. The system also includes a fluid measurement assembly coupled with a portion of the needle to measure pressure of a fluid dispensed in the needle. The pressure measurement assembly is configured to measure (1) a first pressure that is the pressure of the fluid as the fluid is dispensed through the needle at a constant rate; (2) a second pressure that is a pressure change when the needle contacts the tissue and the first opening becomes occluded; and (3) a third pressure that is a second pressure change when the needle penetrates the tissue and the aperture becomes occluded.

Independent claim 1 is not obvious over Sicurelli, because Sicurelli does not disclose a fluid measurement assembly configured to measure a pressure that is a pressure change when a needle penetrates a tissue and an aperture in the needle becomes occluded.

Sicurelli does not describe a needle device that involves penetrating tissue. Instead, Sicurelli describes a flexible needle for irrigating and delivering medication to intra-tooth canals. In other words, the canal has already been formed. The needle is being inserted into the canal

(i.e., into a preformed opening). The needle in Sicurelli is not penetrating the tooth or other tissues.

Since Sicurelli does not describe a device that may be used to penetrate tissue, Sicurelli does not disclose a pressure measurement assembly configured to measure pressure changes as a needle penetrates tissue. Sicurrelli is inserted into a preformed canal, therefore, it is not necessary or potentially even feasible for the pressure sensor of Sicurelli to measure a pressure change since presumably there would be no pressure change.

Since Sicurelli is not concerned with measuring pressure changes as its flexible needle is introduced into a preformed tooth canal, there is also no motivation in the reference to configure its pressure sensor to make such measurements. The Patent Office has no basis for the assumption that the pressure sensor of Sicurelli is "fully capable of measuring changes in the fluid flow rate due to its size, shape and ability to work in the environment such as when the fluid is dispensed at a constant rate, when the needle contacts tissue, and when the needle penetrates tissue" as asserted by the Patent Office. Applicant also believes that, with this assumption, the Patent Office is impermissibly taking official notice of facts not of record and therefore requests the Patent Office support its opinion or withdraw it. See MPEP 2144.03 (official notice, unsupported by documentary evidence, should only be taken by the Patent Office where the fact asserted is well known, or is common knowledge in the art, capable of instant and unquestionable demonstration as being well known).

Claims 2-3 and 5-10 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-3 and 5-10 are not obvious over Sicurelli.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 1-10 under 35 U.S.C. §103(a).

D. 35 U.S.C. §103(a): Rejection of Claims 11-12

The Patent Office rejects claims 11-12 under 35 U.S.C. §103(a) as obvious over Sicurelli in view of U.S. Patent No. 6, 546,787 of Schiller, et al. (Schiller). Schiller is cited for teaching a computer processor and feedback system to be used in connection with needle systems.

Claims 11-12 depend from claim 1 and therefore contain all the limitations of that claim. As noted above, Sicurelli does not teach or provide any motivation for a system including a fluid pressure measurement assembly that measures a pressure change when a needle penetrates tissue and an aperture becomes occluded as recited in claim 1. The computer processor and visual feedback system of Schiller does not cure the defect of Sicurelli. Accordingly, claims 11-12 are not obvious over the combination of references.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 11-12 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,
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CERTIFICATE OF TRANSMISSION
I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon — 10/20/06
Nedy Calderon — Date